FEB 21 2001

510(k) SUMMARY K003252
COMPLETE® brand Multi-Purpose Solution

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

Paul J. Nowacki
Manager
Regulatory Affairs
Allergan
2525 Dupont Drive
Irvine CA 92612

Phone: (714) 246-6761
Fax: (714) 246-4272

Summary Prepared: February 1, 2001

(a)(2) **Device Trade Name:** COMPLETE® brand Multi-Purpose Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** The purpose of this application is to request a determination of substantial equivalence for modified lens care directions for lenses replaced at least every 30 days. COMPLETE® brand Multi-Purpose Solution used with the modified lens care regimen is substantially equivalent to other multipurpose lens care products currently on the market and meets parameters outlined in FDA's May 1, 1997, Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products.

(a)(4) **Device Description:** COMPLETE® brand MULTI-PURPOSE Solution is a sterile, isotonic, buffered, solution containing hydroxypropyl methylcellulose as a lubricant, preserved with polyhexamethylene biguanide 0.0001%, a phosphate buffer, Poloxamer 237 as a surfactant, edetate disodium as a chelating agent, sodium chloride, potassium chloride, and purified water. COMPLETE® brand MULTI-PURPOSE Solution contains no chlorhexidine or thimerosal.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

(a)(6) **Comparison of Technological Characteristics:** There are modified lens care instructions but no changes to the product formulation or other technological characteristics.

(b)(1) **Discussion of Nonclinical:**

Cleaning Effectiveness: We compared the proposed regimen with the current regimen and a marketed competitor. Group I and IV lenses were examined for surface deposits and general cleanliness over a 30 day/30 cycle period which included a soak in artificial tears. Results show that COMPLETE® brand Multi-Purpose Solution used with the modified regimen is equivalent to the control products/regimens and is an effective cleaner for soft (hydrophilic) contact lenses.

Microbiological Studies: We evaluated disinfection efficacy using studies outlined in FDA's May 1, 1997, Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products, but adapted as requested by FDA for the modified regimen. COMPLETE® brand Multi-Purpose Solution meets FDA requirements for disinfection of contact lenses when used with the modified lens care regimen. The product also meets USP Modified criteria for Preservative Effectiveness Testing and USP Sterility test requirements as shown by previous testing.

Toxicological Studies: We performed a 28-day rabbit study in which the ocular effects of COMPLETE® brand Multi-Purpose Solution was evaluated in regimens both with and without the modified lens care regimen, and with and without weekly enzymatic cleaning. The study lasted 28 consecutive days. There were no clinically significant regimen-related ocular findings associated with the modified lens care regimen.

(b)(2) **Discussion of Clinical Data:**

This three-month, randomized, investigator-masked, parallel group study compared the acceptability and safety of two COMPLETE® brand Multi-Purpose Solution regimens; the current labeled instructions and those with a modified lens care regimen. Subjects used daily wear hydrogel contact lenses, replaced monthly. Our goal was to show non-inferior acceptability measured by the mean change from baseline in lens comfort.

Results show that, under conditions of monthly replacement, the use of COMPLETE® in the modified lens care regimen is safe, acceptable and substantially equivalent to COMPLETE® used in a standard regimen, based on comparable data observed for the safety variables of slit lamp examination findings, study lens-corrected visual acuity and the incidence of adverse events. Additionally, the modified regimen met the primary acceptability variable of non-inferiority for change from baseline in lens comfort score at Day 90 (primary analysis timepoint). This is supported by the high completion rate of subjects in the modified treatment group as well as the low overall incidence of slit lamp findings and symptoms of discomfort. Regarding subject acceptability, some variables (e.g., lens comfort, symptoms of discomfort, acceptability questionnaires) suggest that the modified "no rub" regimen may not be preferred by some lens wearers on an everyday basis.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** We conclude that the safety, efficacy and acceptability of COMPLETE® brand Multi-Purpose Solution, when used with the modified regimen, is substantially equivalent to multipurpose solutions currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Allergan, Inc.
C/O Paul Nowacki
Manager, Regulatory Affairs
2525 Dupont Dr.
Irvine, CA 92612

Re: K003252
Trade Name: COMPLETE® brand Multi-Purpose Solution (Modified lens care directions)
Regulatory Class: II
Product Code: LPN
Regulation: 886.5928
Dated: January 5, 2001
Received: January 8, 2001

Dear Mr. Nowacki:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER:
(IF KNOWN): K003252

DEVICE NAME: COMPLETE® brand Multi-Purpose Solution

INDICATIONS FOR USE:

COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

_____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ✓
(Per 21 CFR 801.109 (Optional Format 1-2-96)

Karen Warburton

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003252